



K 060728

**510(k) Summary**

03/15/06

**NovaBone Putty – Bioactive Synthetic Graft****1. Submitter Information:**

Name: NovaBone Products, LLC  
Address: 13709 Progress Boulevard, #33  
Alachua, FL 32615  
Telephone: (386) 462-7660  
Facsimile: (386) 418-1636  
Contact: David M. Gaisser

**2. Name of Device:**

Trade Name: NovaBone Putty – Bioactive Synthetic Graft  
Common Name: Osteoconductive Bone Void Filler  
Synthetic Resorbable Bone Graft Material  
Classification Name: Unknown

**3. Legally Marketed Predicate Device:**

Predicate #1: NovaBone – Resorbable Bone Graft Substitute -  
[K021336]  
Predicate #2: Exactech Resorbable Bone Paste - [K020078]  
Predicate #3: Grafton DBM - [K051195]

**4. Device Description**

NovaBone Putty is an osteoconductive, bioactive, bone void filler device. It is composed of a calcium-phosphorus-sodium-silicate (Bioglass) particulate mixed with a synthetic binder that acts as a temporary binding agent for the particulate. The particulate and binder are provided premixed as a pliable cohesive material. On implantation, the binder is absorbed to permit tissue infiltration between the Bioglass particles. The particles are slowly absorbed and replaced by new bone tissue during the healing process.

**5. Intended Use**

NovaBone Putty is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. NovaBone Putty is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

NOVABONE PRODUCTS, LLC

13709 PROGRESS BLVD., #33 • ALACHUA, FL 32615 • (386) 462-7660 • FAX (386) 418-1636

www.novabone.com

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## **6. Technological Characteristics**

The technological characteristics of the NovaBone Putty device are similar to those of the predicates. The device and the predicates are designed as osteoconductive space-filling devices to be gently packed into defect sites and used as non-structural scaffolds for the body's natural healing and bone regeneration process. The device indications are the same as for the predicates.

The primary component of NovaBone Putty is identical to the bioactive glass (45S5 Bioglass) particulate found in the NovaBone predicate. This synthetic material is both biocompatible and osteoconductive. The NovaBone Putty includes a synthetic binder as an inert carrier for ease of handling and delivery, forming a premixed cohesive material. The binder is biocompatible and is absorbed after implantation, opening space between the bioactive glass particles for cell infiltration and bone formation. The bioactive glass particulate remains for a longer post-implantation period, acting as a scaffold for bone ingrowth. This particulate is absorbed and replaced by new bone tissue.

## **7. Warnings and Precautions**

NovaBone Putty does not possess sufficient mechanical strength to support load-bearing defects prior to hard tissue ingrowth. In cases of fracture fixation or where load support is required, standard internal or external stabilization techniques must be followed to obtain rigid stabilization in all planes.

NovaBone Putty is intended for use by clinicians familiar with bone grafting and internal/external fixation techniques. NovaBone Putty must not be used to gain screw purchase or to stabilize screw placement.

## **8. Complications**

Possible complications are the same as to be expected of autogenous bone grafting procedures. These may include: superficial wound infection, deep wound infection, deep wound infection with osteomyelitis, delayed union, loss of reduction, failure of fusion, loss of bone graft, graft protrusion and / or dislodgement, and general complications that may arise from anesthesia and / or surgery.

## **9. Conclusion**

NovaBone Putty is claimed to be substantially equivalent to the NovaBone, Exactech Resorbable Bone Paste, and Grafton DBM predicate devices as a non-structural osteoconductive bone void filler for osseous defects. *In vivo* performance data were presented. Additional supporting *in vitro* data were supplied.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 1 2006

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NovaBone Products, LLC  
c/o Mr. David M. Gaisser  
VP, Operations/RA/QA  
13709 Progress Boulevard #33  
Alachua, Florida 32615

Re: K060728

Trade/Device Name: NovaBone Putty – BioActive Synthetic Graft

Regulation Number: 21 CFR 888.3045

Regulation Name: Bone Void Filler

Regulatory Class: Class II

Product Code: MQV

Dated: March 15, 2006

Received: March 17, 2006

Dear Mr. Gaisser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

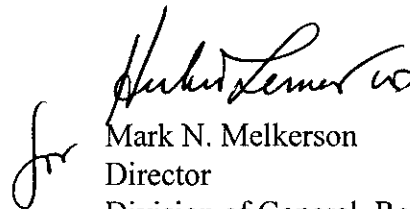
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Mr. David M. Gaisser

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", is written over a large, stylized "for" in cursive.

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

### STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): \_\_\_\_\_

Device Name: \_\_\_\_\_ NovaBone Putty II – Bioactive Synthetic Graft \_\_\_\_\_

**Indications For Use:**

NovaBone Putty – Bioactive Synthetic Graft is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. NovaBone Putty is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

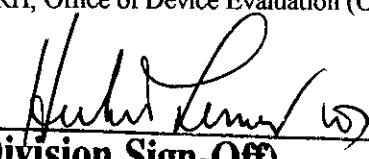
Prescription Use XX

OR  
(Per 21 CFR 801.109)

Over-The-Counter Use \_\_\_\_\_

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

510(k) Number K060728